



ENVIRONMENTAL PROTECTION AGENCY

Notice of availability of Microbial Risk Assessment Guideline: Pathogenic Microorganisms with Focus on Food and Water

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: The U.S. Environmental Protection Agency (EPA) and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture are announcing the availability of the *Microbial Risk Assessment Guideline: Pathogenic Microorganisms with Focus on Food and Water* (MRA Guideline). The MRA Guideline will improve transparency in the way that the two federal agencies conduct microbial risk assessment and also promote consistency in approaches and methods. The MRA Guideline can be applied to similar scenarios involving microbial contamination, and it will serve a resource for federal government risk assessors, their agents, contractors, and for other members of the risk assessment community. When appropriate, the EPA intends to use the guidance prospectively when conducting risk assessments.

DATES: The document, *Microbial Risk Assessment Guideline: Pathogenic Microorganisms with Focus on Food and Water* will be available on July 31, 2012.

Addresses: A downloadable version and supporting materials are available on-line at <http://www.epa.gov/raf/microbial.htm>.

FOR FURTHER INFORMATION CONTACT: Dr. Michael W. Broder, Risk Assessment Forum, Office of the Science Advisor (8105R), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460. His telephone number is (202) 564-3393. His email address is broder.michael@epa.gov.

Internet: The document can be downloaded on-line at <http://www.epa.gov/raf/microbial.htm>.

SUPPLEMENTARY INFORMATION: Risk assessment is used by federal agencies and other entities as a systematic way to prepare, organize, and analyze information to help make informed regulatory decisions, establish programs, and prioritize research.

In 1983, *Risk Assessment in the Federal Government; Managing the Process* was published by the National Research Council (NRC) of the National Academy of Science to formalize the risk assessment process for chemicals in the environment and provide a basic framework that federal agencies could apply when conducting risk assessments. As the use of risk assessment as a tool to assist the federal government in its decision-making process has grown, it became apparent that the 1983 NRC framework document, which was designed to address chemical contaminants, was not as useful for microbial risk assessment. Agencies conducting quantitative microbial risk assessment had to individually modify the 1983 framework to meet their specific needs. As a result, there existed no consistent approach to conducting microbial risk assessment among federal agencies.

The EPA initiated the process of developing a microbial risk assessment guideline and engaged FSIS to co-lead the project. They were joined by scientists from other federal agencies in establishing a collaborative effort to develop this guideline. Clear and credible microbial risk assessment methods will leverage limited resources, promote efficiencies, improve transparency with stakeholders, and encourage joint interaction among agencies.

The MRA Guideline facilitates the systematic and transparent consideration of all relevant factors that impact the risk assessment, and also facilitates reproducible risk evaluation. Using this guideline, agencies assessing a similar microbial medium or pathogen are able to more readily compare and contrast the details and assumptions of their assessment to another agency's assessment. Although the focus of this guideline is microbial contamination of water and food, it will also be useful for microbial risk assessment in a wide range of media and scenarios. The MRA Guideline applies to viruses, bacteria, protozoa, and fungi that are or maybe pathogenic to humans.

EPA released a draft of the document for public comment in July, 2011(76 FR 44586). EPA received two public comments – one from a member of the public and another from a foreign government authority responsible for the assessment of similar health risks in their country. All comments received by the comment period closing date were shared with an external peer review panel for their consideration and considered when revising the document. The MRA Guideline is available at: <http://www.epa.gov/raf/microbial.htm>; the peer review panel's comments and EPA's response to comments can also be found at the same link.

Dated: July 13, 2012.

Glenn Paulson,
Science Advisor.

[FR Doc. 2012-18543 Filed 07/30/2012 at 8:45 am;
Publication Date: 07/31/2012]